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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,791	11/20/2003	Kevin R. Scifert	P-20152.00	8594
27581	7590	10/18/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			MANUEL, GEORGE C	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,791

Applicant(s)

SEIFERT ET AL.

Examiner

George Manuel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 9-20 and 22-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Heil et al (WO 99/53993).

Referring to claims 1, 22, 27 and 30, Heil et al teach an implantable defibrillation lead for the right ventricle that contains a fixation element, a defibrillation electrode, and a sensor (see page 3, lines 26-33; page 4, lines 3-7; and figures 5 and 12). It is inherent the sensor is adapted to function in a high flow region, i.e. the ventricle. With reference to claims 2 and 25, a portion of the defibrillation electrode is placed along the septal wall of the right ventricle when the fixation element is coupled to the endocardial surface in proximity to the right ventricular apex (see figures 5 and 12). Regarding claim 3, the distal tip contains a pacing/sensing electrode that can be positioned from the distal end of the defibrillation electrode by a distance of preferably 1-3 centimeters (see page 8, lines 14-17). The lower end of this range falls within the upper limit of the

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range taught by Applicant. With regard to claims 4 and 28, Heil et al also teach an alternative embodiment in which the shocking electrode is positioned into the anterior groove of the right ventricular out-flow tract against the septum (see page 16, lines 29-32).

Referring to claims 5 and 26, Heil et al teach the pacing/sensing electrode can be implanted along the septal wall of the right ventricle, and depending upon the length of the first defibrillation coil electrode, a portion of the electrode extends along the endocardial wall of the right ventricle (see page 11, lines 10-21 and figure 5). While Heil et al do not teach explicitly that the fixation element couples the lead to the endocardial surface along a right ventricular outflow tract, a defibrillation electrode length, distance to between the electrode and tip, and distance between the defibrillation electrode and the sensing electrode such that the maximum lengths would cause the fixation element to be placed along a right ventricular outflow tract. With reference to claims 6-7 and 9-10, Heil et al do not teach the specific ranges taught by Applicant. However, Heil et al do teach a range of 1-10 centimeters (see page 4, lines 14-17). Regarding claim 12, Heil et al teach a second defibrillation electrode that is positioned within a right atrial chamber or a major vein leading to the right atrial chamber of the heart (see page 4, lines 8-26).

With regards to claims 13 and 23, the lead is placed such that the sensor would be located below the tricuspid valve (see figures 5 and 12). Regarding claims 14 and 24, Heil et al teach positioning the lead in various ways against the septal wall that contains the ventricular outflow tract (see page 16, lines 29-32). Referring to claims 15-

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18, Heil et al teach a preformed bend between the sensor and the defibrillation electrode and tip that enables the sensor to be placed against the septal wall and the defibrillation electrode to be placed along the ventricular apex and a right ventricular lateral wall (see figure 5 on page 11, lines 10-21 and lines 32-33 and page 12, lines 1-5). With reference to claims 19 and 20, Heil et al teach using a tubing to protect the lead and sensors (see page 13, lines 4-10 and page 21, lines 7-12 and figures 6A and 8). Regarding claim 29, the positioning of the lead taught by Heil et al comprises advancing the distal tip toward the apex, withdrawing a stylet, and pushing the lead body into the ventricle (see page 25, lines 3-18). While Heil et al do not teach explicitly using the stylus to position and shape the lead as claimed in claim 29, Heil et al do teach using the stylus to position and shape and teach the positioning and shaping of the lead as claimed by Applicant. Therefore, it is inherent that the stylus would position and shape the lead in the manner as described by Applicant and Heil et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil et al (WO 99/53993).

Heil et al disclose the claimed invention except for the range of approximately 10 cm to approximately 12 cm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a range of the sensor from the distal end being approximately 10 cm to approximately 12 cm. Since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233 and MPEP 2144.05.

Regarding claim 11, Heil et al teach the device and method described above, but do not teach an electrode pair on the distal tip that contains an electrode that contains anode and cathode. Heil et al do teach that the prior art discloses an endocardial lead that features a porous tip electrode which is a tripolar, tined, endocardial lead with a porous tip electrode that serves as the cathode for intracardiac right ventricular electrogram rate sensing and pacing and has a distal electrode serving as the anode (see page 2, lines 24-32). Heil et al teach that using such a lead is the easiest and most convenient way to perform the implantation of a fully transvenous system (see page 2, lines 22-24). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to combine the lead taught by Heil et al with an anode and cathode pair because using such an electrode pair is the easiest and most convenient way to perform the implantation of a fully transvenous system.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heil et al (WO 99/53993) in view of Ferek-Petric (US 5,271,392).

Heil et al teach the lead described above, but do not teach using polyurethane for the lead body. Ferek-Petric does teach using polyurethane because it is an insulative material and is biocompatible (see column 8, lines 4-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the lead disclosed by Heil et al with the body constructed of polyurethane because it is insulative and biocompatible.

Response to Arguments

Applicant's arguments filed 6/23/06 have been fully considered but they are not persuasive. Heil et al do disclose a sensor positioned in a high flow region of a heart because the ventricles of the heart are high flow regions.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
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